UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ROD HOFTS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	CASE NO. 1:08-cv-0855-DFH-TAB
	)	
HOWMEDICA OSTEONICS CORPORATION,	)	
	)	
	)	
Defendant.	)	

ENTRY ON DEFENDANT'S MOTION TO DISMISS

In 1996, the Supreme Court held that lawsuits brought under state law against medical device manufacturers who submit "premarket notification" to the Food and Drug Administration are not preempted by 21 U.S.C. § 360k(a) when liability is premised on theories that the device was defective and unreasonably dangerous and that the manufacturer failed to use reasonable care in the device's design, manufacture, assembly, and sale. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 481, 494-95 (1996). In 2008, the Supreme Court held that lawsuits brought under state law against medical device manufacturers who obtain federal "premarket approval" are preempted by section 360k(a) when liability is premised on violations of state law requirements that are in addition to or different from federal requirements regulating the devices. *Riegel v. Medtronic, Inc.*, 552 U.S. —, 128 S. Ct. 999 (2008). Neither case held that state lawsuits premised on violations of federal law are preempted under section 360k(a). Even so, some

medical device manufacturers, including defendant Howmedica Osteonics Corporation in this case, have tried recently to stretch *Riegel* beyond recognition by transforming its protection for FDA-approved devices that *comply* with federal law into a grant of civil immunity for FDA-approved devices that *violate* federal law. As explained below, the court rejects that reading of *Riegel* and holds that plaintiff Rod Hofts may pursue civil claims against Howmedica based on theories that Howmedica failed to comply with federal requirements for manufacturing the replacement hip joint implanted in him.

Defendant Howmedica developed, tested, and manufactured the Trident Ceramic Acetabular System, an artificial hip replacement device used in patients requiring total hip arthroplasty or replacement. On April 16, 2004, a Trident was implanted in plaintiff Rod Hofts. Sometime after the Trident was implanted in him, Hofts "heard an audible sound emanating from the location of the Implanted Trident," and he "experienced constant irritation and discomfort." Amended Complaint ¶¶ 19-20. Hofts has brought suit against Howmedica for its manufacture of and its representations about the Trident. He originally brought ten claims. He has dismissed three, leaving seven for disposition by the court. Those claims are strict liability for defective manufacture (Count I), negligent manufacture (Count IV), breach of express warranty (Count V), breach of the implied warranty of fitness for a particular purpose (Count VI), breach of the implied warranty of merchantability (Count VII), and violations of the Indiana

commercial fraud statute, Indiana Code § 35-43-5-3(a)(9) and (a)(2) (Counts VIII and IX).

Howmedica moved to dismiss each of Hofts' remaining claims pursuant to Rule 12(b)(6) for failure to state a claim upon which relief can be granted. Based on *Riegel*, Howmedica argues that all of Hofts' claims should be dismissed as expressly preempted under the Medical Device Amendments Act of 1976, 21 U.S.C. § 360k. In the alternative, Howmedica argues that Hofts' negligence, breach of express warranty, and statutory deception claims should be dismissed because they are not properly pled and that his breach of express warranty and statutory deception claims should be dismissed because they are outside the applicable statute of limitations. For the following reasons, Howmedica's motion has been denied.[1]

Standard of Review

In ruling on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the court must assume as true all well-pleaded facts set forth in the complaint, construing the allegations liberally and drawing all inferences in the light most favorable to the plaintiff. See, *e.g., Jackson v. E. J. Brach Corp.*, 176 F.3d 971, 977-78 (7th Cir. 1999); *Zemke v. City of Chicago*, 100 F.3d 511, 513

[1]The court ruled from the bench on Howmedica's motion after oral argument held on January 16, 2008. This entry explains the court's reasoning in more detail.

(7th Cir. 1996); *McMath v. City of Gary*, 976 F.2d 1026, 1031 (7th Cir. 1992). A plaintiff must "raise a right to relief above the speculative level" by pleading "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, —, —, 127 S.Ct. 1955, 1959, 1960 (2007). Dismissal is warranted if the factual allegations, seen in the light most favorable to the plaintiff, do not plausibly entitle the plaintiff to relief. *Id.* at 1968-69.

Discussion

I. *Medical Device Preemption After Riegel*

The Medical Device Amendments of 1976 (MDA) contains an express preemption clause stating that

> no State or political subdivision may establish or continue in effect with respect to a device intended for human use any requirement – (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Defendant argues that Hofts' theories seek to impose state requirements that are different from or in addition to the requirements already established by the FDA in its approval and regulation of the Trident hip implant. The court concludes that Hofts' claims do not seek to impose legal requirements that are different from or in addition to the FDA's requirements. His claims are not preempted under the MDA.

The Supreme Court recently considered the preemptive impact of the MDA in *Riegel v. Medtronic, Inc.*, 552 U.S. —, 128 S. Ct. 999 (2008). The balloon catheter at issue in *Riegel*, like the Trident here, was a "Class III" device, meaning that it had received the highest level of federal oversight provided by the FDA. Also like the Trident, the balloon catheter in *Riegel* reached the market only after premarket approval ("PMA"), a "rigorous" process. *Riegel*, 128 S. Ct. at 1004. In the PMA process, the manufacturer must provide to the FDA "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of such device" and "specimens of the labeling proposed to be used for such device." 21 U.S.C. §§ 360e(c)(1)(C) & (F). The FDA may grant premarket approval only if, after "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," it finds that there is a "reasonable assurance" of the device's "safety and effectiveness." 21 U.S.C. §§ 360c(a)(2)(C), 360e(d)(1)(A). Once a device has received premarket approval, the manufacturer must obtain FDA approval before making any changes in the device's design specifications, manufacturing processes, labeling, or any other attribute that would affect its safety or effectiveness. 21 U.S.C. § 360e(d)(6)(A)(i).

In *Riegel*, the plaintiffs alleged that the balloon catheter manufactured by defendant Medtronic was designed, labeled, and manufactured in breach of duties imposed by New York common law and that the defects caused the plaintiffs to suffer severe and permanent injury. *Riegel*, 128 S. Ct. at 1005. The district court

held that the MDA preempted the Riegels' claims of strict liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing and sale of the catheter. *Id*. at 1005-06. The district court also held that the MDA preempted the Riegels' negligent manufacturing claim, but only to the extent that the claim was *not* premised on the theory that Medtronic had violated federal law. *Id*.

But the district court had allowed the Riegels to go forward on claims that Medtronic was negligent in manufacturing by failing to comply with federal standards and had breached an express warranty. Those claims were not preempted by the MDA. The district court later granted summary judgment on those claims, apparently on the merits, and those claims were not before the Supreme Court. See *id*. at 1006, n.2.

On review, the Supreme Court held that the PMA process imposed federal "requirements" that triggered the preemption clause of the MDA. *Riegel*, 128 S.Ct. at 1007. The Court further held that the tort duties implicit in a finding of liability under the common law claims brought by the Riegels would also constitute "requirements" under the MDA. *Id*. at 1007-08. Ultimately, the Court concluded that to the extent the state tort law underlying the Riegels' claims would require a manufacturer's device to be safer (but perhaps less effective) than the model device approved by the FDA, those requirements would "disrupt[ ] the federal scheme no less than state regulatory law to the same effect." *Id*. at 1008. Thus,

the Court found that the state requirements implicit in the Riegels' common law claims were different from or in addition to the federal requirements and were preempted under the MDA.

The *Riegel* Court took care, however, to limit its holding to claims that the device at issue "violated state tort law *notwithstanding compliance with the relevant federal requirements*." 128 S. Ct. at 1011 (emphasis added). The Court gave lower courts clear instructions for cases like this one, in which plaintiffs allege that a manufacturer has failed to manufacture a device according to the FDA-approved standards and procedures: "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.*, quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). In *Lohr*, the Court had rejected a preemption defense as applied to another medical device (pacemaker leads) where the plaintiff based her claims on allegations that the manufacturer had violated federal regulations. Writing for the Court, Justice Stevens explained the relationship between state and federal law for such claims:

> Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not

> amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

518 U.S. at 495 (reversing dismissal of complaint).[2]

Under 21 U.S.C. § 360k(a)(1), *Riegel*, and *Lohr*, the court must determine whether the federal government has established requirements applicable to the Trident and whether the claims maintained by Hofts are based on Indiana law requirements that are "different from, or in addition to" the federal requirements. Hofts' claims fall into three general categories: tort claims, warranty claims under the Uniform Commercial Code, and criminal commercial fraud claims under Indiana statutory law. Each category is examined in turn.

A. *Defective Manufacture Tort Claims*

Hofts' negligence and strict liability claims (Counts I and IV of his Amended Complaint) stem from his allegations that Howmedica defectively manufactured

[2]The pacemaker leads at issue in *Lohr* had not been approved through the FDA's PMA process. Instead, the FDA confirmed that the leads were "substantially equivalent" to a device that was already on the market through what is known as a "premarket notification" or "§ 510(k) process." *Lohr*, 518 U.S. at 478-79. The section 510(k) approval process is less rigorous than the PMA process, so much so that *Lohr* held that such generally applicable standards are not "requirements" triggering preemption under section 360k(a). *Id*. at 492-93. The Court went on to explain that section 360k(a) does not preempt state rules that merely duplicate federal requirements. *Id*. at 494-95. Thus, the language in *Lohr* discussing parallel claims quoted above applies to the Trident, even though it was approved under a PMA and not a section 510(k) process.

the Trident by violating the FDA's manufacturing requirements. Generally, Hofts alleges that Howmedica

> was negligent in that the [Trident] was unreasonably dangerous and defective because the manufacturing process for the Trident and certain of its components did not satisfy the FDA's PMA standards for the devices; failed the manufacturing processes for the [Trident] and certain of their components to satisfy the FDA's PMA standards for the device resulted in unreasonably dangerous manufacturing defects; and failed to warn of the unreasonable risks created by these manufacturing defects.

Am. Compl. ¶ 52. Specifically, Hofts alleges that "the Implanted Trident was defectively manufactured and not in compliance with [Current Good Manufacturing Practice requirements] approved by the FDA and had an impurity, imperfection, and/or another product defect allowed to be created, contained, or placed within the product in [Howmedica's] manufacturing process," and that this "impurity, imperfection, and/or another product defect was a deviation from [Howmedica's] design and quality manufacturing standards for the Trident approved by the FDA." Am. Compl. ¶¶ 55, 56. These allegations are incorporated into Hofts' negligence claim, which alleges that Howmedica breached its duties "in that it failed to exercise reasonable care and/or was reckless in the testing, manufacture, quality assurance, and sale of the Implanted Trident." Am. Compl. ¶ 93. Unlike the claims the Supreme Court considered in *Riegel*, Hofts bases his tort claims on his allegations that Howmedica failed in its obligation to meet the FDA's requirements, not that Howmedica failed to exceed those requirements or to meet different requirements.

To support its preemption argument, Howmedica relies on the general language supporting preemption in *Riegel*. Howmedica's position is made clear by the following statement it makes in support of its argument for preemption of Hofts' negligence claim: "if a jury finds against [Howmedica] and determines that [Howmedica] was negligent in testing, quality assurance, or the sale of the Trident, the jury would, in effect, conclude that the FDA 'got it wrong' when it determined that the Trident is safe and effective." Def. Br. 9. Howmedica's argument fails to acknowledge the reasoning of *Lohr* or the fact that the specific tort claims addressed in *Riegel* were not based on the defendant's alleged failure to follow federal requirements, but instead were based on the plaintiffs' allegations that Medtronic had breached state tort duties even though it had complied with federal requirements. *Riegel*, 128 S. Ct. at 1006, 1011.

Here it is clear that Hofts bases his tort claims on his allegations that Howmedica failed to meet the FDA's requirements, not on allegations that Howmedica failed to depart from or exceed those requirements. A jury could find that Howmedica breached the duty of care it owed to Hofts by failing to adhere to the FDA's manufacturing requirements without imposing different or additional requirements. See *Lohr*, 518 U.S. at 495. Similarly, on Hofts' strict liability claim, a jury could find that Howmedica's deviation from the FDA's manufacturing requirements was unreasonably dangerous without imposing different or additional requirements. If supported by the evidence, these results would be entirely consistent with the legal presumption that the FDA "got it right" in setting

those requirements. A jury verdict could simply enforce those same federal requirements. The only state law requirements implicit in Hofts' tort claims are thus identical or parallel to the FDA's federal requirements under *Riegel*, so that Hofts' state tort claims are not preempted under section 360k(a).

To support its preemption argument, Howmedica also relies on *Bausch v. Stryker Corp.*, 2008 WL 5157940 (N.D. Ill. Dec. 9, 2008), in which the district court held that another plaintiff's strict liability and negligence claims based on the Trident hip implant were preempted. In following *Riegel* to dismiss the plaintiff's strict liability claims, the court found that Bausch's claims (unlike Hofts' claims) were not based on any allegation that the device violated any FDA regulations. *Id*. at *4. Recognizing the limits of *Riegel*, the *Bausch* court suggested that if the plaintiff's strict liability claims had been premised "in any way" on violations of the FDA's regulations, her claims would have been parallel to the FDA's regulatory scheme and thus would have survived preemption. *Id*. The court then found that Bausch's negligence claim was not based on a duty that was "substantially identical" to the duty imposed by the FDA's regulations, explaining: "Even if there exists a narrow means whereby Bausch could bring a common law claim for negligence solely on the basis of a defendant's violations of FDA regulations, Bausch has not pled such a claim in this case." *Id*. at *6. The court found "no allegations in the complaint that might put Defendants on notice of a claim that is based entirely on a specific defect in the Trident that existed outside the knowledge and regulations of the FDA." *Id*. Regarding Hofts' tort

claims, this court finds otherwise, so that his strict liability and negligence claims are not preempted.

Howmedica also relies on an even more recent decision from the District of Minnesota dismissing claims of manufacturing defects in a medical device. *In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation*, — F. Supp. 2d —, 2009 WL 35467 (D. Minn. Jan. 5, 2009) ("*Medtronic Leads*"). The devices at issue were electrical leads that connect implantable cardiac defibrillators to patients' hearts. Those leads, like the Trident hip implants, were also Class III devices subject to the PMA process. *Medtronic Leads*, 2009 WL 35467, at *1, *4. The plaintiffs' tort claims were premised on alleged violations of the FDA's Current Good Manufacturing Practices (CGMPs) and Quality System Regulations (QSRs). The court acknowledged that Riegel had left open what the court called a "back door" for claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's PMA. *Id*. at *3. The court found that the plaintiffs had failed to unlock that so-called "back door" for parallel requirements by alleging manufacturing violations. The court found that the CGMPs and QSRs on which the plaintiffs' tort claims were based were generic, generally applicable requirements. Although the device at issue was subject to a PMA, the court found that because the CGMPs and QSRs lacked any specific requirement applicable to the device at issue, plaintiffs' manufacturing defect claims "would impose requirements 'different from or in addition to' those under federal law." *Medtronic Leads*, 2009 WL 35467 at *8.

The decision to dismiss the manufacturing defect claims in the *Medtronic Leads* litigation seems to have turned on whether the plaintiffs pled their claims of manufacturing defects with sufficient specificity. See *id*. at *8-*9. The court wrote:

> Merely alleging that Medtronic failed to comply with the CGMPs/QSR by using spot welding is insufficient without some factual detail about *why* that violates federal standards. Instead, Plaintiffs were required to point to something in the CGMPs/QSR precluding the use of spot welding in order to state a manufacturing-defect claim that is "plausible on its face."

Id. at *9, citing and quoting *Bell Atlantic v. Twombly*, 127 S. Ct. at 1964-65, 1974. In response to plaintiffs' argument that they could not be more specific without discovery, the court also noted that plaintiffs' counsel had asserted earlier that they did not need discovery to address preemption. *Id*. at *9, n.14.

This court respectfully suggests that this is an unusually stringent application of *Twombly* and Rule 8 of the Federal Rules of Civil Procedure at the motion to dismiss stage. Manufacturing defect claims are not subject, for example, to the "particularity" pleading requirements of Rule 9. By way of comparison, in *Lohr*, the Supreme Court reversed dismissal of similar claims, even though "the precise contours of their theory of recovery have not yet been defined," because it was clear that the plaintiffs allegations "may include claims that Medtronic has, to the extent that they exist, violated FDA regulations." 518 U.S. at 495.

Plaintiff Hofts' claims and theories are more specific than those that survived dismissal in *Lohr*. *Medtronic Leads* therefore is not persuasive on this point. Here, unlike the plaintiffs in *Medtronic Leads*, Hofts has brought claims premised on Howmedica's alleged failure to manufacture the Trident in accordance with the PMA issued by the FDA. His remaining tort claims (Counts I and IV of his Amended Complaint) are based on Indiana tort requirements that are not "different from, or in addition to" the federal requirements established by the PMA. With discovery, he may or may not be able to prove those claims, but his claims are premised on requirements that are parallel to the federal requirements. His claims are not preempted at the pleading stage. The ability to bring civil claims based on violations of federal requirements is not a "back door" that was inadvertently left open by the MDA and *Riegel*, but a familiar part of the common law: an alleged tortfeasor's violation of the law (a speed limit, a building code requirement, or a PMA requirement) serves as evidence that the defendant breached a duty owed to the plaintiff. See *Lohr*, 518 U.S. at 495 (reversing dismissal on preemption grounds where plaintiff alleged that device manufacturer's violations of federal law caused injury).

If the law were otherwise – if it were as Howmedica argues – then *Riegel* and the MDA would be turned upside down and *Lohr* would be overruled. The MDA, as *Riegel* explained, was intended to protect overall public health and safety by relying on an expert agency to balance overall costs and benefits of medical devices that may do much good and even save lives, but that might not always

work as they are intended to work. See 128 S.Ct. at 1008. As applied in *Riegel*, the MDA protects manufacturers who comply with federal requirements from civil liability based on different or additional standards imposed by states (including juries). But if the MDA were construed as Howmedica argues here, the legislation would be transformed into a grant of immunity from civil liability for manufacturers who violate those same federal requirements. That result was rejected by the Court in *Lohr*, and neither the MDA nor *Riegel* supports it.

B. *Breach of Express Warranty*

Hofts' breach of express warranty claim (Count V) alleges that the device implanted in his hip failed to meet the promises of the Trident's label and package inserts. Howmedica argues that these claims are also preempted under *Riegel* because the label was approved by the FDA in the PMA process. Howmedica argues that without a finding of preemption, the warranty at issue would impose additional or different requirements than those imposed by the FDA. Howmedica has confused Hofts' express warranty claim with a defective labeling claim, which would be preempted under *Riegel*. Hofts does not allege that the Trident's FDA-approved label was defective. Hofts is perfectly happy with the label. He contends only that the device implanted in his hip should fit the description on that label. He claims that the Trident did not live up to the FDA-approved promises contained in its label and that he was harmed as a result. Am. Compl. ¶¶ 98-101. As previously noted, the Supreme Court in *Riegel* did not address express

warranty claims. The Seventh Circuit has rejected arguments like Howmedica's. Because express warranties "arise from the representations of the parties and are made as the basis of the bargain between them," a "state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA" and therefore may not be preempted. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997) (allowing such claims, but affirming summary judgment for defendant where plaintiffs had not been able to support the claim with evidence). Accordingly, the court finds that Hofts' breach of express warranty claim is also a parallel claim and is not preempted.

C. *Breach of Implied Warranty*

The FDA's own regulations explicitly restrict the reach of the MDA's preemption clause from state law claims brought under regulations of general applicability, including the Uniform Commercial Code. The regulations specifically note that breach of implied warranty claims are not preempted under section 360k(a). See 21 C.F.R. § 808.1(d)(1).[3] Without attempting to distinguish the

[3]The regulation states:

> There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g. requirements such as general electrical (continued...)

FDA's regulation, Howmedica relies on *Mitchell* for its argument that Hofts' breach of implied warranty claims (Counts VI and VII) are preempted. In *Mitchell*, the Seventh Circuit explained: "A state judgment for breach of implied warranty *that rested on allegations about standards other than those permitted by the FDA* would necessarily interfere with the PMA process and indeed, supplant it." 126 F.3d at 915 (emphasis added). Howmedica has failed to demonstrate at the pleading stage that Hofts' allegations of breach of the implied warranties of fitness for a particular purpose and merchantability "rest on allegations about standards other than those permitted by the FDA." Without such a showing, and in light of the FDA's regulation specifically permitting breach of implied warranty claims, the court denies Howmedica's motion to dismiss Hofts' implied warranty claim as preempted. It will remain to be seen whether Hofts can come forward with evidence that bases this claim on violations of federal requirements, but the claim survives at the pleading stage.

D. *Unfair Trade Practices Statutes*

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[3](...continued)
codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

21 C.F.R. § 808.1(d)(1). The *Riegel* Court criticized this regulation as in tension with the statutory language, but the Court did not take a clear position on the status of the regulation. See 128 S. Ct. at 1010-11. Because the regulation explicitly seeks to preserve breach of implied warranty claims and has not been definitively found to be contrary to the statute, this court declines to reject all reliance on the regulation for guidance on Hofts' implied warranty claims at the pleading stage.

Section 808.1(d)(1) of the FDA regulations under the MDA also specifically permits state law unfair trade practices claims. Even so, Howmedica argues that Hofts' deceptive practices claims under Ind. Code § 35-43-5-3(a)(9) and (a)(2) (Counts VIII and IX) are preempted under *Riegel*.[4] Howmedica argues that the PMA process regulates labeling and dissemination of information regarding the safety and effectiveness of the Trident, that claims that seek to impose different or additional requirements to the Trident are preempted under Riegel, and that Hofts' deceptive practices claims seek to impose such additional or different requirements. Def. Br. 15. Howmedica has failed to demonstrate at the pleading stage that Hofts' allegations of violations of the Indiana statutes "rest on allegations about standards other than those permitted by the FDA." Without such a showing, and in light of the FDA's regulation specifically permitting claims for breaches of state deceptive practices statutes, the court also denies Howmedica's motion to dismiss Hofts' deceptive practices act claims. Again, however, it will remain to be seen whether Hofts can come forward with evidence that bases this claim on violations of federal requirements.

II. *Adequacy of Pleadings and Statute of Limitations*

[4]Under the Indiana statute, a person commits a Class A misdemeanor by "knowingly or intentionally mak[ing] a false or misleading written statement with intent to obtain property, employment, or an educational opportunity," Ind. Code § 35-43-5-3(a)(2), or by "disseminat[ing] to the public an advertisement that the person knows is false, misleading, or deceptive, with intent to promote the purchase or sale of property or the acceptance of employment," Ind. Code § 35-43-5-3(a)(9).

Howmedica also argues that Hofts' claims of negligence, breach of express warranty, and deceptive practices must be dismissed because he did not plead them adequately. Def. Br. 9-10, 13-14, 16-17. Specifically, Howmedica argues that Hofts' negligence claim is not supported by his Amended Complaint because he failed "to allege that Howmedica deviated from the manufacturing processes approved by the FDA during the PMA process." *Id*. at 9-10. Hofts satisfied this requirement by incorporating his allegations that Howmedica "was negligent in that the [Trident] was unreasonably dangerous and defective because the manufacturing process for the Trident and certain of its components did not satisfy the FDA's PMA standards for the devices" and "the manufacturing processes for the [Trident] and certain of their components [failed] to satisfy the FDA's PMA standards for the device resulted [sic] in unreasonably dangerous manufacturing defects." Amended Complaint ¶ 52; see also Amended Complaint ¶ 91 (incorporating same into negligence claim and allegations presented under Count IV). This is sufficient to satisfy Hofts' obligation to put Howmedica on notice of the nature of his claim and to plead enough facts to state a plausible claim to relief. See *Twombly*, 127 S. Ct. at 1974. As noted, defective manufacturing claims are not subject to the heightened pleading requirements of Rule 9 of the Federal Rules of Civil Procedure. Additional detail can be provided, if the evidence supports it, through discovery and further development of the case. It is not reasonable to expect a plaintiff to be able to specify in his complaint exactly how a product defect occurred, though Hofts has identified in his complaint a number of publicly known problems with the Trident. Cf. *Medtronic,*

Inc. v. Lohr, 518 U.S. at 495 (reversing dismissal of less specific claims). The court denies dismissal on this ground.

Howmedica also argues that Hofts' breach of express warranty claim must be dismissed because Hofts failed to allege that the express warranty at issue became the "basis of the bargain" between the parties. Def. Br. 14. Hofts' pleading is sufficient to state a claim. Hofts stated, in part, that "in [the Trident's] labeling, [Howmedical] expressly represented and warranted that the Implanted Trident was safe and effective for 'painful, disabling joint disease of the hip resulting from: Non-inflammatory degenerative arthritis (osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, pelvic fracture, failed fracture fixation, or diastrophic variant).'" Am. Compl. ¶ 98. Although Hofts does not expressly plead that this alleged warranty became the basis for the bargain, he has presented sufficient information from which Howmedica could have – and, indeed, does have – "fair notice of what the . . . claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957). After all, the point of the FDA-approved labels is to provide accurate information to doctors and patients that they can rely upon in buying and using medical devices. Hofts has satisfied his *Twombly* obligation to plead a plausible claim for relief. Howmedica's motion to dismiss this claim on this ground fails.

Regarding the deceptive practices claims, Howmedica argues that Hofts fails to identify the advertisements or written statements at issue, and fails to allege

how any such information was misleading or deceptive. Def. Br. at 16-17. Again, under *Twombly*, Hofts is obliged to plead enough facts to state a plausible claim to relief, meaning that Hofts is obligated to provide "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence [of the claim]." *Twombly*, 127 S.Ct. at 1965. If Hofts is unable to support his claim with evidence, his deceptive practices claims may be dismissed later. For now, he has satisfied his obligation to put Howmedica on notice of his claim and has raised a plausible claim to relief to satisfy the requirements of Rule 8(2)(a) and *Twombly*.

Finally, Howmedica argues that the applicable statutes of limitations operate to bar Hofts' express warranty and deceptive practices claims. Def. Br. at 14, 17. Howmedica may prove to be correct on this issue, but without more detailed information about the timing of Hofts' discovery of the alleged defects in the device, dismissal on the pleadings would be premature.

Conclusion

For the foregoing reasons, Howmedica's motion to dismiss Counts I and IV through IX of Hofts' Amended Complaint has been denied.

So ordered.

Date: February 11, 2009

David F Hamilton

DAVID F. HAMILTON, CHIEF JUDGE
United States District Court
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